Allergy Therapeutics

Biomarker data confirm VLP Peanut hypoallergenicity

3 August 2021

- The VLP-Peanut 001 *ex vivo* biomarker study carried out in conjunction with Imperial College London has reported positive results. This study, focused on evaluating safety, confirmed both the hypoallergenicity of this first VLP (virus-like particle) based peanut allergy vaccine candidate and the proposed design of the Phase I PROTECT first-in-human trial (outlined in our July 2021 Update), on track to initiate in Q122.
- Human blood samples from peanut allergic individuals were used to evaluate an extensive range of functional and molecular biomarkers and assess the potential for an allergic reaction following dosing with VLP Peanut. The study achieved its primary outcome, confirming VLP Peanut was hypoallergic: basophil activation and histamine release post challenge was 24-fold lower vs with recombinant peanut extract. Analysis of secondary endpoints is yet to be completed.
- This new data will be included in the VLP Peanut IND application, which will be submitted to the FDA in late-2021, supplement the existing preclinical research package that demonstrated sustained immunological protection following peanut exposure after one single vaccination. An extensive multiple dose toxicology study with the VLP Peanut vaccine candidate has also completed, using the maximum subcutaneous doses expected to be administered in the PROTECT Phase I trial.
- The VLP Peanut vaccine candidate is a novel immunogenic, protective, and non-reactogenic short-course subcutaneous vaccine based on immunologically optimized Cucumber Mosaic Virus-derived VLPs (CuMVTT) that display the major peanut allergen (Ara h 2) on its surface. Further information will be presented by Allergy Therapeutics on its VLP Peanut vaccine candidate and VLP technology at a key opinion leader event and investor day in September 2021.

Price	26.85p
Market Cap	£172.3m
Primary exchange	AIM
Sector	Healthcare
Company Code	AGY
Corporate client	Yes

Company description:

Allergy Therapeutics specialises in the diagnosis and treatment of allergy. The existing European business generates c £80m annual sales. Near-term R&D efforts are focussed on the Pollinex Quattro platform, whilst in the medium-term the VLP platform is highly promising.

Trinity Delta view: The positive biomarker study results pave the way for an IND submission in late-2021 and Phase I trial start in Q122. As peanut allergy is one of the most common food allergies, and a leading cause of severe and fatal food-induced anaphylactic reactions, it was imperative to establish that the VLP Peanut vaccine candidate is hypoallergic. The data also increase confidence in the clinical relevance of the encouraging preclinical data, although it will be the results of the PROTECT trial that confirm this. With US patents granted, and applications in the national phase in other regions, Allergy Therapeutics is now able to make further VLP-related disclosures at its KOL event. Ahead of this, and top-line results of the Grass MATA MPL G309 exploratory field study anticipated in calendar H221, we continue to value Allergy Therapeutics at £344.5m (53.8p/share). Our SOTP includes a DCF of the commercial operations (£89.7m or 14.0p/share), an rNPV of the R&D pipeline (£210.3m, or 32.8p/share), and net cash (6.9p/share). Positive clinical data from the VLP Peanut and Grass MATA MPL programmes has the potential to unlock further upside.

Analysts

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